BIO-DETEK
INCORPORATED

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510(k) Summary: K112660

Rev. 3

Submitter's Name and Address:
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Date Summary Prepared: April 4, 2012

Device Name: PocketCPR® (Part #2132)

Classification Name: Cardiopulmonary Resuscitation Aid; Class III (21 CFR 870.5200)

Device Description: Effective cardiopulmonary resuscitation (CPR), when administered quickly after the on-set of cardiac arrest, is effective at saving lives and enabling complete neurological recovery, especially when followed by early defibrillation.

The PocketCPR® was developed to provide users with real-time feedback during the administration of CPR, to assist CPR instructors during class exercises, and to provide CPR students with verbal instructions and feedback for at-home practice. When the PocketCPR is turned on, the default protocol being driven by the 2010 American Heart Association's (AHA) Guidelines, reminds the user to call for help. Once placed on the patient's chest and chest compressions have begun, PocketCPR generates a metronome at the recommended rate of chest compression, gives verbal and visual feedback on the quality of CPR being delivered and reminds the user to give two breaths after every 30 compressions. Measurement of actual chest wall movement is made by a state-of-the-art accelerometer micro-chip and microprocessor performing continuous analysis.

The predicate PocketCPR (2047) in K071321 is compliant to the AHA 2005 Guidelines while the proposed PocketCPR (2132) in this submission is compliant to the AHA 2010 Guidelines in the default "Normal Operating Mode" when turned "On".

A plus "+" feature has been added to the Normal Operating Mode to address the caregiver that turns the unit "On", places the device on the patient's chest and commences directly into chest compressions. During the initial power-on protocol the device intuitively monitors for compression recognition of 1.2" or greater. The verbal prompt "Call for Help" will be dropped to allow advancement to the "Start CPR" prompt. This "+" feature will automatically go into chest compression assistance, same as predicate, giving instructions for "Push Harder" as needed and "Good Compressions" when done to correct depth. It also maintains communicating "Open Airway – Give Two Breaths" after each sequence of 30 compressions, same as predicate.

Another plus "+" in the proposed device is an additional guidance source to assist the caregiver in selecting proper orientation of the device when placed on a patient's chest. To best take advantage of the LED's visual cadence and prompting of one LED flashing for "Push Harder" and all four flashing for "Good Compressions" the proper or upright orientation of the device allows the caregiver maximum visual assistance. We have added a "Patient Side" label to the center of the bottom outer surface to direct the caregiver to apply that surface on the patient's chest. The device will also prompt "Analysis Halted" if improper orientation has occurred and will stay silent awaiting proper orientation, hence "Patient Side" label, which when proper orientation occurs the device will then prompt "Start CPR and proceed into CPR assistance sequences.

"Silent Mode" is an operational optional mode both in the predicate PocketCPR and the proposed in this submission for use in training sessions where multiple units are in-play.

NORMAL OPERATING MODE

Start-Up

1. Power On the device by pressing the rubber power button on the side of PocketCPR (marked with a circle and vertical line in the middle).
2. Allow device to Power Up and perform its system checks.
3. Place device in the center of the chest as shown on label.
4. Follow the verbal prompts to:
    - "STAY CALM"
    - "CHECK RESPONSIVENESS"
    - "CALL FOR HELP"
    - "OPEN AIRWAY" "+"
    - "CHECK BREATHING" "+"
    - "START CPR"
5. Place the heel of one hand on the device and the second hand on top so both hands are overlapped.
6. Begin chest compressions, allow for "Full Release" on "UP" stroke.
7. In the Normal Operating Mode "+" feature, the verbal prompts identified with a "+" are over-ridden to advance into chest compression assistance earlier for those caregivers commencing directly into chest compressions.

8. Begin chest compressions, allow for "Full Release" on "UP" stroke.

9. After 18 seconds, representing 30 compressions, follow the verbal prompts to:
   - "OPEN AIRWAY"
   - "GIVE TWO BREATHS"

10. Continue CPR chest compressions following the metronome and light prompts to ensure proper depth and rate. Cycles of 30 compressions and 2 ventilations are recommended or continuous chest compressions if you are unwilling or unable to provide ventilations, or if an advanced airway has been secured.

SILENT MODE
Start-Up

1. Power On the device by pressing ***and holding in*** the power button on the side of the device. After hearing the verbal prompt, "STAY CALM.", wait a full second before releasing the power button.

2. The device metronome will begin to flash, indicating that the device is ready for CPR to begin, allow for "Full Release" on "UP" stroke.

Substantial Equivalence:

Part Number (P/N) 2132 for PocketCPR, which represents the version in this submission, is substantially equivalent to its predecessor, PocketCPR P/N 2047, cleared on 510(k) K071321, which incorporated the 2005 AHA Guidelines. The 2132 version of PocketCPR is programmed to meet the 2010 AHA Guidelines as the default mode. The core technology is the same as its predecessor utilizing an Analog Devices accelerometer, presently an ADXL322 versus the earlier submission which had an ADXL311 accelerometer from the same manufacturer. The Indications for Use are the same as the Predicate.

Indications for Use

PocketCPR Intended Use:

To assist users in the performance of effective CPR on a patient 8 years or older.

PocketCPR Types of Testing

- Bench Testing
  - General Safety
  - Electromagnetic Compatibility
  - Software Performance
  - Water Ingress
  - Vibration Effects
  - Sound Levels of Verbal Prompts & Metronome
- Simulated Use on Computerized Manakin for Data Collection
- Usability Studies performing CPR using PocketCPR
- Biocompatibility of Skin Contact Materials

Conclusion

The PocketCPR® was developed to provide users with real-time feedback during the administration of CPR, to assist CPR instructors during class exercises, and to provide CPR students with verbal instructions and feedback for at-home practice. When the PocketCPR is turned on, the device reminds the user to call for help. Once placed on the patient's chest and chest compressions have begun, PocketCPR generates a metronome at the recommended rate of chest compression, gives verbal and visual feedback on the quality of CPR being delivered and reminds the user to give two breaths after every 30 compressions. Measurement of actual chest wall movement is made by a state-of-the-art accelerometer micro-chip and microprocessor performing continuous analysis.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY 10 2012

Bio-Detek Incorporated
c/o Mr. Robert Morse
Director, Regulatory Affairs
525 Narragansett Park Drive
Pawtucket, RI 02861-4323

Re: K112660
PocketCPR
Regulation Number: 21 CFR 870.5200
Regulation Name: Cardiopulmonary Resuscitation Aid
Regulatory Class: Class III
Product Code: LIX
Dated: May 1, 2012
Received: May 2, 2012

Dear Mr. Morse:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K112660

Rev 3

Device Name: PocketCPR™

PocketCPR Intended Use:

To assist users in the performance of effective CPR on a patient 8 years or older.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X___ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K112660